Docket No. 66790-6411

PATENT

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In re application of: Ewing B. Gourley	:	
Serial No.: 09/710,227	:	Examiner: Porter, Rachel L.
Filed: November 10, 2000	:	Group Art Unit: 3626
For: Method and Apparatus for Processing Pharmaceutical Orders to Determine Whether A Buyer of Pharmaceuticals Qualifies for an "Own Use" Discount	:	

Amended Appeal Brief

Applicant submits the following as its appeal brief in connection with the appeal of the above-referenced patent application.

Table of Contents:

List of References:

USPN 6,003,006 (Colella);

Gardner, J. Pharmaceutical scam: Use audit to detect 'Pyramid Cube Scheme', HFM, September 1982, p. 72-74;

USPN 5,890,129 (Spurgeon)

Table of Cited Authorities:

Federal Courts Case Law:

Abbott Laboratories v. Portland Retail Druggists Association, 425 U.S. 1, 47 L.Ed. 2d 537 (U.S. 1976)

KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007).

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 USPQ 657 (Fed. Cir. 1985)

Exxon Research and Engineering Co. v. U.S., 60 USPQ2d 1272 (Fed. Cir. 2001)

Fiers v. Revel, 25 USPQ2d 1601 (Fed. Cir. 1993)

Lighting World Inc. v. Birchwood Lighting Inc., 72 USPQ2d 1344 (Fed. Cir. 2004).

In re Mercier, 185 USPQ 774 (CCPA 1975)

Moore U.S.A. Inc. v. Standard Register Co., 56 USPQ2d 1225 (Fed. Cir. 2000)

In re Paulsen, 31 USPQ2d 1671 (Fed. Cir. 1994)

Pickholtz v. Rainbow Technologies Inc., 62 USPQ2d 1340 (Fed. Cir. 2002)

Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169 (Fed. Cir. 2007)

Young v. Lumenis Inc., 83 USPQ2d 1191 (Fed. Cir. 2007)

British Telecommunications PLC v. Prodigy Communications Corp., 62 USPQ2d 1879 (S.D.N.Y. 2002),

BPAI Case Law:

Ex Parte Keung, 17 USPQ2d 1545, 1547 (B.P.A.I. 1989)

Ex Parte Maizel, 27 USPQ2d 1662, 1665 (B.P.A.I. 1992)

Manual of Patent Examining Procedure:

Sections 2141.03, 2173.02, and 2173.05(b)

i. Real Party in Interest:

The real party in interest is Health Resources, USA, L.L.C., which is the assignee of the subject application.

ii. Related Appeals and Interferences:

None

iii. Status of Claims:

As set forth in the table below, (1) claims 1-23, 25, 27-30, 32-49, 62-66, and 68-80 (which represent all of the currently pending claims) stand rejected, and (2) claims 24, 26, 31, 50-61, and 67 stand canceled from the application.

Claim	Status	Claim	Status	Claim	Status	Claim	Status
1	Rejected	21	Rejected	41	Rejected	61	Canceled
2	Rejected	22	Rejected	42	Rejected	62	Rejected
3	Rejected	23	Rejected	43	Rejected	63	Rejected
4	Rejected	24	Canceled	44	Rejected	64	Rejected
5	Rejected	25	Rejected	45	Rejected	65	Rejected
6	Rejected	26	Canceled	46	Rejected	66	Rejected
7	Rejected	27	Rejected	47	Rejected	67	Canceled
8	Rejected	28	Rejected	48	Rejected	68	Rejected
9	Rejected	29	Rejected	49	Rejected	69	Rejected
10	Rejected	30	Rejected	50	Canceled	70	Rejected
11	Rejected	31	Canceled	51	Canceled	71	Rejected
12	Rejected	32	Rejected	52	Canceled	72	Rejected
13	Rejected	33	Rejected	53	Canceled	73	Rejected
14	Rejected	34	Rejected	54	Canceled	74	Rejected
15	Rejected	35	Rejected	55	Canceled	75	Rejected
16	Rejected	36	Rejected	56	Canceled	76	Rejected
17	Rejected	37	Rejected	57	Canceled	77	Rejected
18	Rejected	38	Rejected	58	Canceled	78	Rejected
19	Rejected	39	Rejected	59	Canceled	79	Rejected
20	Rejected	40	Rejected	60	Canceled	80	Rejected

iv. Status of Amendments:

No amendment has been filed subsequent to the Final Office Action.

v. Summary of Claimed Subject Matter:

Independent claims 1 and 62 (as well as all of the claims dependent therefrom) address a method whereby retail pharmacies can be provided with "own use" discounts for certain ones of their pharmaceutical purchases. As described in the subject patent application, the inventor believes that retail pharmacies have been unable to obtain "own use" discounted pharmaceuticals because pharmaceutical sellers fear that retail pharmacies will "divert" the "own-use"-discounted pharmaceuticals to end users who are not "own use" discount eligible. (See Patent Application; p. 2, lines 12-17; p. 4, lines 14-21). The inventor believes that this inability to purchase "own use"-discounted pharmaceuticals is experienced by retail pharmacies even when those retail pharmacies are purchasing pharmaceuticals on behalf of "own-use" eligible institutions such as nursing homes. (See Patent Application; p. 3, lines 30-32). This is a great problem for the nursing home industry, where an estimated 45% of nursing homes purchase their pharmaceuticals from retail pharmacies, thereby unnecessarily contributing to this nation's crippling health care costs. (See Patent Application; p. 3, line 30- p. 4, line 2; p. 4, lines 14-21).

For a better understanding of this problem, a background discussion of the "own use" discount and the issue of "diversion" is in order. As stated in the patent application:

> The Robinson-Patman Price Discrimination Act, 15 USC §13(a), generally makes it unlawful for one engaged in commerce to discriminate in price between different purchasers of like commodities where, among other things, "the effect of such discrimination may be substantially to lessen competition." Abbott Laboratories v. Portland Retail Druggists Association, 425 U.S. 1, 3-4, 47 L.Ed. 2d 537, 543 (1976). This United States law essentially prevents pharmaceutical sellers from selling a given type of pharmaceutical at regular price to one buyer and then selling that same type of pharmaceutical at a discounted price to another buyer. However, an exception to the Robinson-Patman Act exists stating that "nothing in the [Robinson-Patman Act], shall apply to purchases of their supplies for their ***own use*** by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit." 15 USC §13c. Because of this exception, hospitals, nursing homes, long term health care facilities, and the like are eligible for purchasing pharmaceuticals at a discounted price -- an "own use" discount -- when they are buying pharmaceuticals on behalf of their patients or in some situations, their employees. Therefore, when nursing homes purchase pharmaceuticals on behalf of their patients, they are eligible to purchase such pharmaceuticals from the pharmaceutical manufacturer at a discounted price. (See Patent Application; p. 1, line 2 – p. 2, line 7).

However, merely because nursing homes are legally entitled to receive "own use" discounts does not mean that they will in fact receive those discounts in the real world. In the real world, most nursing homes purchase their pharmaceuticals from middle men. (See Patent Application; p. 2, lines 8-12). Because these middle men also purchase pharmaceuticals on behalf of buyers that are not "own use" eligible, pharmaceutical sellers are highly reluctant to sell "own use"-discounted pharmaceuticals to such middle men for fear of "diversion" by the middle men. (See Patent Application; p. 2, lines 12-17).

As an example of "diversion", assume middle man X buys 10,000 units of Pharmaceutical Y from Pharmaceutical Seller Z at an "own use"-discounted price of $1/unit, wherein the normal non-discounted price to middle men is $2/unit, and wherein the normal sales price to a retail seller is $2.25/unit. In an exemplary diversion scenario, Middle Man X sells the 10,000 units to a buyer who is not "own use" eligible at a price of $1.75/unit, for a profit of $7,500. In doing so, Middle Man X has defrauded Pharmaceutical Seller Z of $10,000 and has trebled their profits, which would have been $2,500 had Pharmaceutical Seller Z known that Middle Man X was selling the pharmaceuticals to a buyer not eligible for the "own use" discount.

Against this backdrop, and as stated above, the inventor notes that a large percentage of nursing homes, which are "own use" eligible institutions, are unable to purchase pharmaceuticals at an "own use"-discounted price because they purchase their pharmaceuticals through retail pharmacies. Because retail pharmacies supply large amounts of pharmaceuticals to walk-in customers who are not "own use"-eligible, the inventor believes that pharmaceutical sellers are unwilling to sell "own use"-discounted pharmaceuticals to retail pharmacies even when the retail pharmacy is supplying those pharmaceuticals to a nursing home. (See Patent Application; p. 3, line 20 – p. 4, line 2). These retail pharmacies can be contrasted with "closed pharmacies" which are generally given "own use" discounts by pharmaceutical sellers.

> A closed pharmacy is a pharmacy that supplies pharmaceuticals to institutions such as hospitals or nursing homes, but does not sell pharmaceuticals to walk-in customers. Because these closed pharmacies have an exclusive customer list of customers who are eligible to buy pharmaceuticals at an "own use" discount, pharmaceutical manufacturers are willing to sell pharmaceuticals to these closed pharmacies at a discounted price. That is, pharmaceutical manufacturers are not

> overly worried that the "closed pharmacy" will sell discounted pharmaceuticals at a regular price to customers ineligible for a discount, because the "closed pharmacy" has virtually no such customers. (See Patent Application; p. 3, lines 11-19).

In an effort solve this problem, claim 1 recites a method whereby orders from certain buyers are audited to determine whether the order is entitled to an "own use" discount. By following the auditing method recited in claim 1, the buyer can verify to a seller's satisfaction that the pharmaceuticals being ordered are in fact destined for "own use" eligible customers. Claim 1 recites the step of receiving a pharmaceutical order from a buyer, wherein "said buyer comprises one from a group consisting of (1) ***an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home***, and (2) ***at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home***..." (See Patent Application; e.g., p. 6, lines 3-8; Figures 5-6 (emphasis added)).

Claim 1 further recites the step of "receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer". This report comprises data that evidences the buyer's eligibility for an "own use" discount. (See Patent Application; p. 10, line 1 – p. 13, line 23; Figures 2(a)-4).

Upon receipt of the report, claim 1 recites the step of "comparing said order with said associated report to determine whether said associated report supports said order". (See Patent Application; p. 17, line 1- p. 20, line 10; Figure 9 (steps 446-450)).

Lastly, claim 1 recites the step of "responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an 'own use' discount." While a one-to-one correspondence between the order quantity and the quantity documented by the report would result in a determination that the report supports the order, the inventor further notes that a tolerance can optionally be incorporated into this status determination. (See Patent Application; p. 7, lines 28-31; p. 17, lines 8-27; p. 19, lines 2-5; Figure 9 (step 452)).

Through these steps, claim 1 recites a new, useful and nonobvious method by which a reliable determination can be made that pharmaceuticals purchased by retail pharmacies with nursing home customers are entitled to an "own use" discount.

Claim 62 recites a method similar to claim 1, wherein claim 62 recites a step of determining an "own use" discount status for a "proposed 'own use' purchase by a buyer", wherein the buyer "comprises at least one selected from the group consisting of (1) a ***retail pharmacy*** that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) ***an entity comprising a plurality of said retail pharmacies***" (emphasis added). Claim 62 further recites that this "own use" discount status determination is made "on the basis of a comparison between the proposed purchase and information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with the pharmaceutical by the buyer".

Independent claim 30 addresses an auditing system for making such an "own use" status determination for pharmaceutical orders from a buyer. Claim 30 recites that software executed by a processor within the system be configured to "confirm whether said buyer is any of a group consisting of (a) ***an entity comprised of at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home, and (b) ***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home..." (emphasis added). The "first input", "second input", and "output" recited in claim 30 are depicted in Figure 8 and described in the corresponding text in the specification. The processor and software limitations are shown in Figure 7 (auditor computer 300), Figure 8 (as discussed above), and Figure 9. (See Patent Application; e.g., Figures 7-9; p. 19, lines 19-27; p. 21, line 32 – p. 22, line 1; p. 24, lines 21-22).

Independent claims 16 and 69 recite a method and system respectively, wherein two forms of documentation are needed to audit an order to establish the order's entitlement to an "own use" discount. (See Patent Application, e.g., p. 16, lines 15-17; p. 13, lines 18-23). Independent method claim 16 recites the steps of:

> receiving ***a first associated report*** summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;
>
> receiving ***a second associated report*** summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals by said buyer;
>
> analyzing ***said first associated report and said second associated report to determine an extent to which they support said order***; ... (emphasis added).

Claim 69 similarly recites that a computer be configured to base its "own use" audit "on at least two types of audit data that are compared to said order." (See Patent Application; Figure 7 (computer 300).

As examples, the specification identifies a preferred embodiment wherein a retail pharmacy listing and a physician's order sheet (POS) from a nursing home are used as these first and second associated reports (and two forms of audit data). (See Patent Application; p. 13, lines 18-23).

By basing its audit on two reports/two forms of audit data, the invention of claims 16 and 69 improves the reliability of the audit. (See Patent Application, e.g., p. 16, lines 15-17).

Independent claim 76 recites a method that includes the following steps:

> receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;
> receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;
> comparing said order with said associated report to determine whether said associated report supports said order;
> responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount; and
> responsive to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

Thus, claim 76 further recites that orders can be adjusted so that they are supported by the report that evidences the buyer's entitlement to an "own use" discount. This aspect of claim 76 is disclosed in the specification at p. 6, lines 20-23, p. 7, line 31 – p. 8, line 2, and Figure 9 (steps 454-456)). By adjusting orders in response to the audit comparison, the method of claim 76 allows buyers to maximize their entitlement to "own use" discounts even if the order is somewhat inaccurate with respect to its "own use" entitlement and/or the order pools orders for "own use" eligible and "own use" ineligible customers. Independent claim 75 recites a computer that is configured to perform such order adjustments. (See Patent Application; e.g. Figure 7 (computer 300); Figures 8 and 9 (which disclose the software executed by computer 300); p. 19, lines 19-27; p. 21, line 32 – p. 22, line 1; p. 24, lines 21-22).

vi. Grounds of Rejection to be Reviewed on Appeal:

I. Whether claim 69 is unpatentable under 35 U.S.C. 112, first paragraph as being based on a nonenabling disclosure.

II. Whether claims 37, 43-44, and 69-74 are unpatentable under 35 U.S.C. 112, second paragraph as being indefinite; and more specifically:

(a) whether claims 37 and 43-44 are indefinite; and

(b) whether claims 69-74 are indefinite

III. Whether claims 1, 9-10, 12-13, 15-23, 25, 27-30, 32-37, 45-49, 62-66, and 68-80 are unpatentable under 35 U.S.C. 103 over Colella (USPN 6,003,006) in view of Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'"); and more specifically:

(a) whether claim 1 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(b) whether claim 62 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(c) whether claim 65 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(d) whether claim 66 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(e) whether claim 30 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(f) whether claim 76 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(g) whether claim 75 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(h) whether claims 28, 48, 68, and 73 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner;

(i) whether claims 29, 49, and 77 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner;

(j) whether claim 16 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(k) whether claim 17 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(l) whether claim 69 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(m) whether claims 70 and 79 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner; and

(n) whether claim 64 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner.

IV. Whether claims 2-8, 11, 14, and 38-44 are unpatentable under 35 U.S.C. 103 over Colella in view of Gardner and further in view of Spurgeon (USPN 5,890,129).

vii. Argument:

Applicant will now address the various rejections made in the Final Office Action and explain why these rejections must be reversed on appeal.

I. Claim 69 does not violate 35 USC 112, first paragraph because claim 69 is not a single element "means plus function" claim; the recited "computer configured to ..." limitation in claim 69 does not invoke 35 USC 112, paragraph 6 because the term "computer" connotes sufficient structure to avoid classification as a "means plus function" limitation.

The Final Office Action rejected claim 69 under 35 U.S.C. 112, first paragraph "because the specification does not reasonably provide enablement for a claim covering every conceivable means for achieving the recited purpose". (See Final Office Action; p. 2). Claim 69 reads as follows:

> 69. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:
> a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount, said audit being based on at least two types of audit data that are compared to said order.

This rejection of claim 69 is premised on the Examiner's interpretation of the "computer" limitation of claim 69 as being a "means plus function" limitation. (See Final Office Action; p. 2). Under such an interpretation, the Examiner asserts that claim 69 is a single element "means plus function" claim in violation of 35 U.S.C., first paragraph.

However, Applicant respectfully submits that it is improper to interpret the "computer" limitation of claim 69 as a "means plus function" limitation. Applicant notes that claim 69 fails to recite the term "means", thereby triggering a strong presumption that the "computer" limitation of claim 69 is not a "means plus function" limitation.

> [A] claim term that does not use 'means' will trigger the rebuttable presumption that § 112 ¶ 6 does not apply. [citation omitted] ... The presumption that a limitation lacking the term "means" is not subject to section 112 ¶ 6 can be overcome if it is demonstrated that "the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function'". [citations omitted] Our cases make clear, however, that the presumption flowing from the absence of the term "means" is

> a strong one that is not readily overcome. [citations omitted] Lighting World Inc. v. Birchwood Lighting Inc., 72 USPQ2d 1344, 1348 (Fed. Cir. 2004).

Within this framework, Applicant respectfully submits that the limitation "a computer configured to perform an 'own use' audit..." in claim 69 recites a sufficiently definite structure that can perform the "own use" audit – namely the structure of a "computer". Applicant further submits that the Final Office Action's reliance on Fiers v. Revel, 25 USPQ2d 1601 (Fed. Cir. 1993), Ex Parte Maizel, 27 USPQ2d 1662, 1665 (B.P.A.I. 1992), and Ex Parte Keung, 17 USPQ2d 1545, 1547 (B.P.A.I. 1989) is misplaced as these cases pertain to biotechnology claims in an unpredictable art as opposed to a claim in the computer arts. As recognized in British Telecommunications PLC v. Prodigy Communications Corp., 62 USPQ2d 1879, 1883-84 (S.D.N.Y. 2002), the term "computer" in a claim limitation represents sufficient structure to prevent the claim limitation from being treated as a "means plus function" limitation.

> [T]he "central computer means" is not a means-plus-function claim. The functions of the central computer are stated in the claim language, however, the claim recites the entire structure necessary to perform the claimed function. [citation omitted] ***That structure is a computer***. British Telecommunications, 62 USPQ2d at 1884 (emphasis added).

The court in British Telecommunications reached this conclusion even though the claim limitation at issue used the term "means", thereby triggering the presumption that the "central computer means" was a "means plus function" limitation. Id. at 1883. Thus, with claim 69 the conclusion that the "computer" limitation is not a "means plus function" limitation is further enhanced given that claim 69 operates in an environment that already begins with a strong presumption against treatment as a "means plus function" limitation.

Applicant further notes that the specification describes computers in accordance with their conventional meaning in the art. For example, the specification, with reference to Figure 7, describes an embodiment where a computer 300 is employed to perform "own use" audits. (See Patent Application; p. 20, line 19 et seq.; Figure 7). Moreover, Figure 9 illustrates a flowchart for software that can be deployed on computer 300 to perform an "own use" audit. (See Patent Application; p. 24, line 21 et seq.; Figure 9). Applicant thus uses the term "computer" in claim 69 in accordance with its conventional meaning. The fact that persons having ordinary skill in the art would understand the meaning of a "computer" is further

reinforced by the Federal Circuit decisions In re Paulsen, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (interpreting the claim term "computer" in a claim without even raising the issue of classifying the term "computer" as a "means plus function" limitation) and Pickholtz v. Rainbow Technologies Inc., 62 USPQ2d 1340, 1344-45 (Fed. Cir. 2002) (also interpreting the claim term "computer" in a claim without even raising the issue of classifying the term "computer" as a "means plus function" limitation).

Accordingly, for the foregoing reasons, Applicant respectfully submits that it was error for the Examiner to interpret the "computer" limitation in claim 69 as a "means plus function" limitation, thereby rendering it an error to reject claim 69 as a single element "means plus function" claim. Reversal of this rejection is respectfully requested.

II. The term "sufficient" in claims 37, 43 and 44 does not render those claims indefinite.

The Final Office Action rejected claims 37 under 35 U.S.C. 112, second paragraph "because the term 'sufficient' in claim 37 is a relative term, which renders the claim indefinite". (See Final Office Action; p. 3-4). Claims 43-44 were rejected under the same rationale. The Final Office Action further stated "[t]he term 'sufficient' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (See Final Office Action; p. 4).

Claim 37 reads as follows:

> 37. The pharmaceutical order auditing system of claim 35 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon ***whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers***. (emphasis added).

Claims 43 and 44 include similar limitations.

"Claims are considered indefinite when they are 'not amenable to construction or are insolubly ambiguous .... Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning.'" Young v. Lumenis Inc., 83 USPQ2d 1191, 1197 (Fed. Cir. 2007) (finding that the claim term "...incision in the epidermis *near* the edge of the ungual crest..." is not indefinite). In assessing whether a claim term is indefinite, consideration of intrinsic evidence such as the specification is appropriate. Young, 83 USPQ2d at 1197.

Similarly, as recognized in Section 2173.05(b) of the Manual of Patent Examining Procedure (MPEP):

> When a term of degree is presented in a claim, ***first a determination is to be made as to whether the specification provides some standard for measuring that degree***. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. (See MPEP §2173.05(b) (emphasis added)).

In the indefiniteness rejection of claim 37, the Final Office Action summarily concludes that "the specification does not provide a standard for ascertaining" the meaning of "sufficient" in claim 37. However, Applicant respectfully disagrees. At page 23, lines 7-19, the specification describes what is meant by "a sufficient number of matches" in the context of a "patient identifier comparison".

> Next, the software can compare the patients identified in the order data with the patients identified in the audit data to verify that there is a patient match between the order data and the audit data. ***As previously discussed, the patient data also need not be an exact one-to-one match***, although it would be preferable. ***In such cases, the software can attribute a percentage patient match to the comparison***.
>
> If the software determines that there is a type match, a sufficient size match, and a ***sufficient patient match***, the software can produce a status report indicating that a status determination has been made verifying that the buyer does in fact qualify for purchasing the quantity of pharmaceuticals in the order at a price reduced by an "own use" discount. Of course, if the software determines that there is not a type match, a sufficient size match, or a sufficient patient match, the status report can indicate that a status determination has been made that the buyer does not qualify for the discount based on the original order. (See Patent Application; p. 23, lines 7-19 (emphasis added)).

Thus, the specification provides a clear standard for interpreting the term "sufficient number of matches" in claim 37. As explained in the specification, the term "sufficient number of matches" describes a number of patient identifier matches that are within a defined percentage of all patient identifier matches, thereby providing a tolerance to the patient identifier comparison. The specification further discloses a preferable "sufficiency parameter" for use by the auditing software of Figure 9 having a value of 90% for patient matches. (See Patent Application; p, 24, lines 31-32).

Based on this clear guidance in the specification as to how "sufficient" should be interpreted in claims 37 and 43-44, Applicant respectfully submits that it was error for the Examiner to reject claim 37 and claims 43-44 for indefiniteness. See Young, 83 USPQ2d at 1198 ("When intrinsic evidence resolves the claim construction, a term is not 'insolubly ambiguous,' and thus reference to the prior art is not needed."). As stated in Section 2173.02 of the MPEP:

> The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. ... Some latitude in the manner of expression and the aptness of terms should be permitted even through the claim language is not as precise as the examiner might desire. (See MPEP §2173.02).

Therefore, Applicant respectfully submits that claims 37 and 43-44 comply with 35 USC Section 112, second paragraph. (See also Exxon Research and Engineering Co. v. U.S., 60 USPQ2d 1272 (Fed. Cir. 2001) (holding that the term "sufficient" in a claim did not render the claim indefinite) and Moore U.S.A. Inc. v. Standard Register Co., 56 USPQ2d 1225 (Fed. Cir. 2000) (providing an interpretation for the claim term "distance sufficient" without finding the claim indefinite)).

III. The separately recited terms "computer" and "second computer" in claims 69-74 do not render those claims indefinite.

The Final Office Action rejected claims 69-74 for indefiniteness because these claims recite both "a computer" and "a second computer". (See Final Office Action; p. 4). Claims 69

and 70 (as well as intervening claim 74) read as follows (with the pertinent claim limitations highlighted):

> 69. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:
> ***a computer*** configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount, said audit being based on at least two types of audit data that are compared to said order.
>
> 74. The system of claim 69 wherein said at least two types of audit data comprise:
> a retail pharmacy listing that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals; and
> data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.
>
> 70. The system of claim 74 further comprising:
> ***a second computer*** in communication with ***said computer*** via a network, ***said second computer*** being configured to provide ***said computer*** with said retail pharmacy listing, and wherein ***the computer*** is further configured to perform said "own use" audit by comparing said order with said said retail pharmacy listing.

Applicant notes that claim 70 adds a "second computer" to the system of claim 69. As an initial matter, Applicant notes that the Examiner's indefiniteness rejection of claims 69-74 is entirely inapplicable to claims 69 and 73 because these claims do not recite the "second computer" limitation that the Examiner contends is the source of the indefiniteness. As such, Applicant notes that the indefiniteness rejection of claims 69 and 73 must be reversed for this reason.

Furthermore, while the "computer" recited in claim 69 is configured to "perform an 'own use" audit", the "second computer" added in claim 70 is configured to "provide said computer with said retail pharmacy listing". As such, Applicant respectfully submits that claims 69 and 70 are clear in their recitations of a "computer", a "second computer" and their respective functional operations within the system. With respect to the Examiner's statement that these claims are unclear as to "how many computers are present", Applicant notes that claim 70 clearly recites the presence of two computers. Furthermore, with respect to the Examiner's statement that it is unclear as to which of these computers the term "said

computer" refers, Applicant notes that claim 70 clearly uses the phrase "said second computer" to refer to the "second computer" added by claim 70 while using the phrase "said computer" to refer to the "computer" recited in claim 69. These formulations are made using standard antecedent basis terms common to claims. Therefore, Applicant respectfully submits that the indefiniteness rejections of claims 69-74 is in error and must be reversed.

IV. The Colella and Gardner references fail to render independent method claim 1 obvious because those references fail to render obvious the concept of performing an audit on a pharmaceutical order from a buyer to determine whether the order qualifies for an "own use" discount, wherein the buyer comprises a member of the "group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home".

The Final Office Action rejected independent method claim 1 for obviousness based on the combination of the Colella and Gardner references. The Final Office Action asserted that Colella discloses all aspects of claim 1 with the exception of the step of "making a status determination". (See Final Office Action; pages 5-6). Nevertheless, the Final Office Action found that "Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts", and the Final Office Action further concluded that it would have been obvious to modify Colella's method/system to check/verify whether pharmaceutical purchases qualify for "own use" discounts for the purpose of avoiding legal violations while still enjoying cost containment benefits, as taught by Gardner. (See Final Office Action; p. 6, citing Gardner at page 74, paragraph 4).

However, Applicant respectfully submits that this obviousness rejection is in error. First, the Final Office Action based its rejection on mistaken interpretations of the Colella and Gardner references, both individually and in combination. For example, Applicant respectfully submits that contrary to the assertion on page 5 in the Final Office Action, Colella fails to disclose a step of receiving an order from a buyer, wherein the buyer comprises "an entity comprised of at least one retail pharmacy". Furthermore, Gardner expressly discourages hospitals from selling excess pharmaceuticals to "questionable brokers/business enterprises" who supply "small drugstores" (e.g., retail pharmacies). (See Gardner; p. 74). Gardner

discloses no techniques that can be used to establish that the "questionable brokers/business enterprises" are entitled to an "own use" discount. Instead, Gardner discloses that hospitals should perform audits on their own inventory to ensure that such brokers are not purchasing the hospital's excess pharmaceutical stock. (See Gardner, p. 74, the paragraphs following the "Audit checks to consider").

Second, the Final Office Action based its rejection on a mistaken interpretation of claim 1. Following Applicant's response dated March 14, 2006 to the first Office Action, the Examiner recognized Applicant's arguments that Colella fails to address the issues faced by retail pharmacies. (See Final Office Action, p. 37). However, the Examiner discounted these arguments based on a mistaken interpretation of claim 1 when the Final Office Action stated: "it is noted that the features upon which applicant relies (i.e., the involvement of retail pharmacies) are not recited in the rejected claim(s)." (See Final Office Action, p. 37). Contrary to the Examiner's mistaken assertion, claim 1 does in fact require that the buyer be either ***"an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home" or ***"at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home". These and other errors will be explained in greater detail below.

The Supreme Court recently reinforced that the *Graham* factors still lay the framework for addressing the question of whether a claimed invention is obvious. KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1391 (U.S. 2007). These factors are:

1) "the scope and content of the prior art";
2) the "differences between the prior art and the claims";
3) "the level of ordinary skill in the pertinent art"; and
4) objective evidence of nonobviousness.

Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169, 1174 (Fed. Cir. 2007) (quoting KSR).

(1) The Scope and Content of the Prior Art

Colella discloses a method/system that provides inventory tracking and drug distribution functionality for "health care providers such as hospitals". (See Colella, col. 1, lines 6-16). The basic actors in the Colella system are hospital staff who dispense drugs to patients, the hospital pharmacy which manages the hospital's drug inventory, and a drug distributor which supplies the hospitals' drug needs. Toward this end, Figure 1A of Colella

discloses a system wherein patients' drug needs are entered by nurses through "drug distribution machines" (DDMs) 18 located at nursing stations 16. (See Colella; col. 4, lines 1-7; Figure 1A). The DDMs forward this drug consumption information to the hospital's "central pharmacy computer" (CPC) 20, wherein the CPC runs a Drug Inventory Management Software (DIMS) program to manage the hospital's drug inventory needs. (See Colella; col. 4, lines 7-9; Figure 1A). The CPC can then communicate with a "drug distribution center computer" (DCC) that also runs a DCC counterpart to the DIMS program, wherein the DIMS programs executed by the CPC and DCC can work with each other to automatically supply the hospitals' drug needs based on information collated from the various DDMs 18. (See Colella; col. 4, lines 10-53).

Gardner warns hospitals that the sale of excess drug inventory to "questionable brokers/business enterprises" who supply "small drugstores" may violate a variety of laws. (See Gardner; page 74; Exhibit 1). Gardner describes a "pyramid cube scheme" where such brokers approach "hospital purchasing personnel" in an effort "to convince them [the hospital purchasing personnel] to over-order pharmaceuticals for the purpose of reselling the excess pharmaceuticals to them [the brokers] for a profit, thereby reducing the hospital's costs." (See Gardner; p. 74). Gardner further warns that "[t]he pharmaceutical products selected by the brokers are normally only sold direct or via authorized dealerships to the hospital intended for its own use and not for resale purposes." (See Gardner, p. 74).

> The excess pharmaceuticals, warehoused in the hospital, are then resold and delivered by the brokers to local satellite clinics and small drugstores at a profit to the hospital and the brokers. Although a profit margin is incorporated in the price, the small institutions/businesses are now able to purchase the goods at a lower cost than they would normally pay to the manufacturer or dealerships. The greater the volume ordered by the hospital, the lower the obtainable bid price – the greater the margin for profit. (See Gardner; p. 74).

Gardner notes that such practices raise a number of legal concerns. (see Gardner; p. 74; section entitled "Legal aspects and ramifications").

As a solution to this problem, Gardner advises hospitals to conduct audits for the purpose of identifying whether such "pyramid cube scheme" diversion to "questionable brokers" is occurring. (See Gardner; p. 74 ("This article is intended to encourage hospitals to

double check their internal procedures to ascertain if this practice is occurring. It can be checking using the audit process."). Gardner describes auditing measures that can be used to illuminate whether a hospital is engaging in a "pyramid cube scheme" for diversion in the section entitled "Audit checks to consider". (See Gardner; p. 74). Lastly, Gardner concludes with the teaching:

> A shared purchasing agreement, used legally to obtain preferential prices for goods for one's "own use," is an acceptable approach to cost containment. The "Pyramid Cube Scheme," used as an illegal profit for others, should be discouraged, especially for all tax-exempt hospitals. (See Gardner; p. 74).

Thus, Gardner provides strong teachings that hospitals should not sell pharmaceuticals from their inventory to brokers who supply small drugstores by characterizing such a practice as an illegal pyramid cube scheme.

(2) The Differences Between the Prior Art and Claim 1

Colella fails to disclose an auditing process that compares a pharmaceutical order from a buyer with an associated report to assess whether the order is entitled to an "own use" discount. It is important to note that Colella addresses an inventory tracking/ordering system for hospitals' ***in-house pharmacies***.

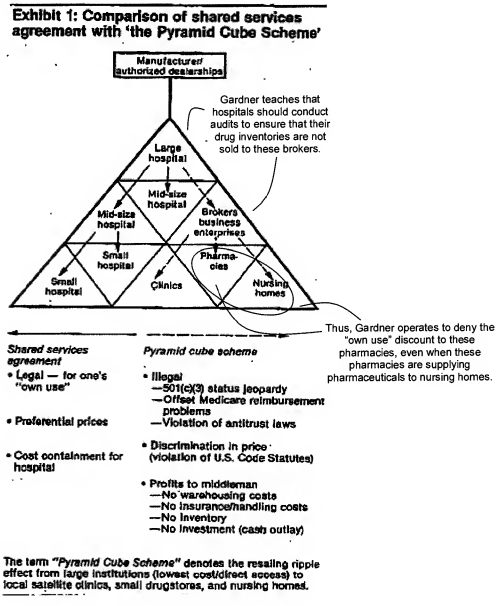
> It has been known for health care providers, such as hospitals, to have ***a pharmacist or pharmacy department within the hospital*** to coordinate the dispensing of drugs to the patients of the health care institution. The pharmacists in such health care institutions have long been burdened with the increasingly complex record keeping and inventory management that results from hospitals caring for hundreds, if not thousands of patients every day. (See Colella; col. 1, lines 13-20 (emphasis added)).

Such in-house pharmacies fall into the class of "closed pharmacies" discussed in the patent application at page 3, lines 11-19 and in Section v above. With a closed pharmacy such as a hospital's in-house pharmacy, sellers are willing to sell "own use"-discounted pharmaceuticals thereto because those closed pharmacies do not have a retail customer base to which the "own use"-discounted pharmaceuticals can be readily diverted. As explained above and in the patent application, sellers such as the "drug distributor" of Colella have been historically unwilling to

sell "own use"-discounted pharmaceuticals to retail pharmacies (as opposed to closed pharmacies) for fear of diversion. The method of claim 1 is expressly limited to an auditing process that enables "one from a group consisting of (1) ***an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home, and (2) ***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home" to purchase "own use"-discounted pharmaceuticals. Thus, even though the Final Office Action asserted that Colella addresses processing orders from a buyer wherein the buyer "includes an entity comprised of at least one retail pharmacy..." (see Final Office Action; p. 5), Applicant respectfully submits that Colella addresses only orders by hospitals' in-house pharmacies who are already presumed entitled to the "own use" discount. The passages cited in the Final Office Action as disclosing the claim limitations relating to the retail pharmacy buyer of claim 1 (Colella at Figures 4 and 6; col. 5, lines 33-43) simply fail to address retail pharmacies in any way.

The Gardner reference also fails to disclose the concept of auditing pharmaceutical orders from buyers, wherein the buyer comprises "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". Gardner addresses tracking pharmaceutical usage within a hospital that has already presumably received an "own-use" discount. Gardner is silent with respect to a process for determining whether an order of pharmaceuticals on behalf of a nursing home but placed by a retail pharmacy (or an entity comprising at least one retail pharmacy) should be deemed eligible for an "own use" discount. Gardner teaches that hospitals should turn away and refuse to sell excess inventory to brokers who supply pharmaceuticals to "small drugstores". (See Gardner; p. 74). To ensure that such brokers are refused business, Gardner teaches that hospitals should audit their own pharmaceutical usage, presumably to uncover whether any sales to brokers are occurring. (See Gardner; p. 74). Thus, while Gardner recognizes the existence of retail pharmacies (namely, the "small drugstores" which are supplied by the "questionable brokers"), Gardner addresses an auditing process for use by a hospital to prevent "own use"-discounted pharmaceuticals from reaching retail pharmacies rather than an auditing process that brings the "own use" discount to certain orders by retail pharmacies.

The Pyramid Cube Scheme exhibit (reproduced below) shown in Gardner serves as a case in point for the shortcomings of the Gardner reference relative to claim 1.



In contrast to the teachings of Gardner, the method of claim 1 addresses a technique for auditing orders from certain buyers to thereby establish those buyer's entitlement to an "own use" discount. In claim 1, the buyer can be a retail pharmacy that supplies pharmaceuticals to

a nursing home, whereas Gardner teaches an auditing process designed to prevent "own use" discounted pharmaceuticals from reaching such retail pharmacies. In claim 1, the buyer can also be an entity that comprises at least retail pharmacy, the at least one retail pharmacy supplying pharmaceuticals to a nursing home (such as a buyer's co-op), which would fall into the forbidden "broker" category in Gardner's "Pyramid Cube Scheme" exhibit.

Furthermore, when considered in combination with each other, the Colella and Gardner references fail to render claim 1 obvious. In combination, Colella's inventory tracking system merely serves as a useful tool for completing some of the "audit checks" listed by Gardner. However, these audits are still being performed, as per Gardner, to prevent the hospital from re-selling its excess inventory while Colella's system functions to automatically regulate the hospital's inventory so that it closely matches hospital needs. This combination still would not yield the method of claim 1, which operates to bring the "own use" discount to an entirely new class of buyers.

There is simply no teaching, suggestion, or motivation evident in the record apart from the inventor's patent application for using an auditing process to establish that an order from a buyer is entitled to an "own use" discount, wherein the buyer is "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home".

While the Final Office Action indicates that the Examiner considered Applicant's previous arguments in this regard, the Final Office Action further indicates that the Examiner discounted these arguments based on a misinterpretation of claim 1. (See Final Office Action; p. 37). In the "Response to Arguments" section of the Final Office Action, the Examiner states:

> (C) Applicant argues that Colella fails to address issues faced by retail pharmacies.
>
> It is noted that Applicant cites pages from the specification to discuss these features. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the involvement of retail pharmacies) ***are not recited in the rejected claim(s)***. (See Final Office Action; p. 37 (emphasis added)).

However, contrary to this erroneous statement by the Examiner, the method of claim 1 is ***expressly limited*** to only orders from a buyer, wherein the buyer is "one from a group consisting of (1) ***an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home, and (2) ***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home" (emphasis added).

While Applicant recognizes that the KSR decision has stressed that a rigid application of the "teaching, suggestion, or motivation" (TSM) test to the question of obviousness is inappropriate, KSR nevertheless notes that the TSM test is a "helpful insight" into the question of obviousness. KSR, 82 USPQ2d at 1396; see also Takeda, 83 USPQ2d at 1174 ("the [KSR] Court indicated that there is 'no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.' [citation omitted] As long as the test is not applied as a 'rigid and mandatory formula, that test can provide 'helpful insight' to an obviousness inquiry.").

Furthermore, when one examines the concerns in KSR with respect to a rigid application of the TSM test, Applicant respectfully submits that the nonobvious nature of claim 1 is further supported. For example, the Supreme Court in KSR stated that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR, 82 USPQ2d at 1395. With respect to claim 1, however, the prior art fails to establish that a predictable result of combining Colella with Gardner will be the extension of the "own use" discount to a buyer that is "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". In fact, an objective review of these references yields no predictions at all with respect to retail pharmacies other than hospitals should audit their inventories to ensure that brokers for such retail pharmacies are not purchasing drugs from those inventories.

Furthermore, the Supreme Court in KSR cautioned against focusing only on the problems/motivations of the inventor/patentee. Id. at 1397. However, even considering the known motivations from Colella and Gardner, the method of claim 1 is not rendered obvious. The combination of Gardner with Colella based on the motivations and teachings found in Gardner and Colella fail to reproduce the claimed invention. The motivation of Gardner is to

prevent pharmaceuticals that have already received an "own use" discount from being sold by hospitals to brokers who supply small drugstores. The primary motivation of Colella is to closely monitor drug inventories. When combined with each other, Colella and Gardner would lead a person having ordinary skill in the art to employ Colella's inventory tracking system to monitor the hospital's drug inventory as part of Gardner's suggested audit to determine whether any drugs are being diverted to "questionable brokers". However, once again, this combination fails to render the inventive method of claim 1 obvious.

Lastly, the Supreme Court in KSR recognized the continued validity of the principle that a strong indicator of nonobviousness are teachings in the prior art that teach away from combining elements. Id. at 1395 (citing U.S. v. Adams, 148 USPQ 479 (U.S. 1966)). In the instant case, Applicant respectfully submits that Gardner teaches away from the invention of claim 1 because Gardner teaches the use of an audit process designed to prevent brokers who supply small drugstores from receiving "own use"-discounted pharmaceuticals, thereby preventing those small drugstores from receiving "own use"-discounted pharmaceuticals. As reflected in the Pyramid Cube Scheme of Exhibit 1 in Gardner, this carte blanche discouragement of discounted sales exists even in situations where those small drugstores are supplying the pharmaceuticals to nursing homes, which are themselves "own use" discount eligible. In direct contradiction to this teaching, claim 1 addresses a method employing an audit process that brings the "own use" discount to parties denied the "own use" discount by Gardner, namely a buyer that is "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". Therefore, Applicant respectfully submits that teachings in Gardner that teach away from the invention of claim 1 further mandate that the Examiner's obviousness rejection of claim 1 must be reversed.

As is well-settled, "*all* of the relevant teachings of the cited references must be considered in determining what they fairly teach to one having ordinary skill in the art. [citations omitted] The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention." In re

Mercier, 185 USPQ 774, 778 (CCPA 1975) (emphasis in original) (*see also* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 USPQ 657,667, 669, fn 33 (Fed. Cir. 1985) (finding error by the district court where the district court's obviousness analysis used the claims as blueprint and failed to give "due consideration for teachings in [the prior art] references that would have led one skilled in the art to find it improper to combine [the prior art] references") A failure to heed these mandates results in an improper obviousness rejection of a claim based on selective hindsight wherein Applicant's claims are used against him as a map to navigate through isolated and unrelated disclosures in the prior art.

(3) Level of Ordinary Skill in the Pertinent Art

As recognized in Section 2141.03 of the MPEP, the prior art itself can indicate the level of ordinary skill in the art. In this case, the prior art Gardner reference is written to persons having ordinary skill in the art who work in hospitals and directs those persons to conduct audits to prevent the sale of pharmaceuticals that have already been purchased at an "own use" discount to brokers who supply small drugstores. Based on this teaching to persons having ordinary skill in the art, Applicant respectfully submits that a person having ordinary skill in the art would not have found claim 1 obvious at the time of invention because Gardner directs such a person to limit the sale of "own use"-discounted pharmaceuticals, not expand such sales to new buyers who Gardner expressly disparages as "questionable brokers" who are seeking to induce hospitals into committing illegal acts.

(4) Objective Evidence of Nonobviousness

Applicant further submits that the Gardner reference serves as objective evidence of nonobviousness for claim 1. As stated above, Gardner teaches that an audit process should be employed to prevent the sale of pharmaceuticals that have already been purchased at an "own use" discount to brokers who supply small drugstores. Gardner makes this teaching even though such small drugstores could be supplying nursing homes with pharmaceuticals, as reflected in the positioning of the "pharmacies" and "nursing home" triangles in the Pyramid Cube Scheme of Exhibit 1. Claim 1, contrary to the teachings of Gardner, is directed toward

an auditing process that brings the "own use" discount to nursing homes who receive their pharmaceuticals from such pharmacies.

Therefore, for the foregoing reasons, Applicant respectfully submits that claim 1 and all of its dependent claims are nonobvious in view of the Colella/Gardner combination.

V. The Colella and Gardner references also fail to render independent claim 62 obvious.

Applicant also notes that independent claim 62 is nonobvious over the Colella/Gardner combination for similar reasons as expressed in connection with claim 1. Applicant further notes that claim 62 is limited to "determining an 'own use' discount status for a ***proposed 'own use' purchase***" of pharmaceuticals by a buyer, wherein the "buyer comprises at least one selected from the group consisting of (1) a retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) an entity comprising a plurality of said retail pharmacies." Applicant further notes that the Colella/Gardner combination fails to address the concept of auditing ***proposed*** orders to assess their "own use" discount eligibility. Instead, the Gardner/Colella combination teaches that Colella's inventory tracking system should be used to conduct an audit for assessing whether pharmaceuticals already purchased at an "own use" discount are being diverted from inventory to "questionable brokers". Therefore, Applicant respectfully submits that independent claim 62 and all of its dependent claims are also nonobvious in view of the Colella/Gardner combination.

VI. The Colella and Gardner references also fail to render dependent claim 65 obvious.

Dependent claim 65 further limits claim 62 (by way of claim 63) to a buyer that is a **retail** pharmacy. As such, Applicant respectfully submits that claim 65 is patentable over the Colella/Gardner combination for the same reasons expressed above in connection with claims 1 and 62. Applicant further notes that the Final Office Action misinterprets the Colella reference in its rejection of claim 65 because Colella addresses the in-house pharmacies of hospitals (i.e., closed pharmacies) rather than a **retail** pharmacy which supplies a hospital, nursing home, or long term health care facility, as required by claim 65.

VII. The Colella and Gardner references also fail to render dependent claim 66 obvious.

Dependent claim 66 further limits claim 62 (by way of claim 63) to a buyer that is an entity comprising a plurality of **retail** pharmacies which supply a hospital, nursing home, or long term health care facility. As such, Applicant respectfully submits that claim 66 is patentable over the Colella/Gardner combination for the same reasons expressed above in connection with claims 1 and 62. Applicant further notes that the Final Office Action misinterprets the Colella reference in its rejection of claim 66 because Colella addresses the in-house pharmacies of hospitals (i.e., closed pharmacies) rather than a **retail** pharmacy which supplies a hospital, nursing home, or long term health care facility, as required by claim 66.

VIII. The Colella and Gardner references also fail to render independent claim 30 obvious.

Independent claim 30 is directed toward an auditing system having a processor configured to execute software to perform an "own use" audit on order data, wherein the software is " configured to (1) confirm whether said buyer is any of a group consisting of (a) an entity comprised of at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (b) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home..." As such, Applicant respectfully submits that claim 30 is patentable over the Colella/Gardner reference for the same reasons expressed above in connection with claim 1.

IX. The Colella and Gardner references fail to render independent claim 76 obvious because those references fail to render obvious the concept of, as part of an auditing process assessing whether a pharmaceutical order is entitled to an "own use" discount, adjusting the order's quantity such that the order's adjusted quantity matches a quantity that is supported by the "associated report" which evidences a need "own use" pharmaceuticals.

The Final Office Action rejected independent claim 76 for obviousness based on the combination of the Colella and Gardner references. The rejection of claim 76 incorporates the rationale for rejecting claims 1 and 28. In rejecting claim 28, the Final Office Action asserted that col. 6, line 65 through col. 7, line 28 and col. 8, lines 59-67 of Colella disclose the concept of adjusting orders to match a report that summarizes the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by the buyer.

Thus, with respect to the scope and content of the prior art, Applicant repeats the observations made above regarding Colella and Gardner. Applicant further notes that the passages cited in Colella in the rejection of claim 28 pertain to features of Colella that track pharmaceutical usage recorded through DDMs such that orders with the appropriate quantities are placed with the distributor. (See Colella; col. 6, line 65 – col. 7, line 28; col. 8, lines 59-67).

The paragraph at col. 6, line 57 through col. 7, line 6 of Colella addresses the use of a percentage threshold to determine when it is time to order a new "unit" of drugs. Thus, if the drug is kept in 100 count bottles, the use of an 80% threshold would operate such that a new unit of that drug is not ordered until 80 tablets have been reported as consumed through the DDMs.

The paragraphs at col. 7, lines 7-20 of Colella address the use of a "track holdover" field for tracking scenarios where an order results in a drug supply greater than the expressed need. Thus, from the example above, where a 100 count bottle of tablets was ordered because 80 tablets had been reported as consumed through the DDMs, a holdover count of 20 tablets will be applied to future usage to determine when a new order is needed. Thus, with a holdover quantity of 20, the DDMs would need to report the consumption of 100 tablets before hitting the 80% threshold again.

The paragraphs at col. 7, lines 21-28 of Colella address the use of the "track holdover" field for tracking scenarios where a need is expressed for a drug that is below the ordering threshold, wherein the system will remember this need and apply it toward future needs of the drug. Thus, if a need is expressed for only 20 tablets, no order will be placed because of the 80% threshold. However, if the DDMs later report the consumption of an additional 60 tablets, the system will apply the holdover quantity of 20 to the new quantity of 60 to find that a new order should be placed because the 80% threshold has been reached.

There are a number of differences between claim 76 and the Colella/Gardner combination. First, Applicant notes that the orders in Colella are not audited to assess whether they are entitled to an "own use" discount because they are presumed to be entitled to such a discount by virtue of the fact that a hospital's in-house pharmacy is placing the order. The addition of Gardner to Colella operates to perform audits on orders that have already been filled to assess whether diversion from a hospital's inventory is occurring. The role of this

audit is not to adjust the quantity in an order because Colella's system is already configured to generate orders that closely match patient needs by basing orders on the inputs through the DDMs.

Second, claim 76 requires that an order for a quantity of a pharmaceutical be received, and further requires that this order be adjusted as a result of the "own use" auditing process. Colella, on the other hand, describes a system whereby the orders are initially formulated with the appropriate quantities such that no further adjustments are necessary. As taught by Colella, the "track holdover" quantity that is maintained by the inventory management system allows any overstock amounts "to be deducted ***before an order is placed***." (See Colella; col. 8, lines 59-67 (emphasis added)). There is simply no teaching, suggestion, or motivation in the record for a method which (1) audits a pharmaceutical order that has already been placed to determine whether the order is supported by the "associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer", and (2) responsive to a determination that the order is not supported by the associated report, adjusting the order such that it is supported by the associated report (e.g., lowering the order quantity). Moreover, the Final Office Action provides no rationale as to why a person having ordinary skill in the art would find claim 76 obvious given the lack of teachings, suggestions, and motivations in Colella and Gardner as to order adjustment.

Therefore, Applicant respectfully submits that the obviousness rejection of claim 76 is improper and must be reversed.

X. The Colella and Gardner references also fail to render independent claim 75 obvious.

Applicant notes that independent claim 75 includes similar limitations to claim 76. Claim 75 further recites that the order adjustment involves adjusting the order's quantity to a subquantity thereof as a result of the auditing process. As explained above in connection with claim 76, the Colella/Gardner references are silent with respect to the concept of adjusting an order's quantity based on an audit process because the Colella/Gardner combination operates to produce orders that do not need adjustment since the order is originally placed with a quantity that is based on an inventory management system that closely track the needs of patients within a hospital. Gardner thus applies to the Colella system only to audit existing inventory

to detect whether diversion is occurring (e.g., diversion of the overstock amounts defined by the "track holdover" parameters).

XI. The Colella and Gardner references also fail to render dependent claims 28, 48, 68 and 73 obvious.

Applicant further notes that dependent claims 28, 48, 68, and 73 also recite limitations similar to claims 75 and 76. As such, Applicant respectfully submits that claims 28, 48, 68, 73, 75, and 76 (and all claims dependent therefrom) are patentable over the Colella/Gardner combination for the reasons expressed above in connection with claims 75 & 76.

XII. The Colella and Gardner references also fail to render dependent claims 29, 49, and 77 obvious.

Dependent claims 29, 49, and 77 require that a "stand by requirement" for the buyer be calculated. The specification discusses this feature at page 18, line 7 – page 19, line 5 and at page 25, lines 4-14 (see also Figure 9). Through this feature, adjustments to orders can be made so that a nursing home supplied through the buyer will have a sufficient stock of pharmaceuticals on hand to meet the demand of expected new patients.

The Final Office Action cites Colella at col. 6, line 65 – col. 7, line 28 and col. 8, lines 59-67 for disclosing this feature. However, these passages, which are summarized above in Section IX do not involve calculating stand by requirements, but rather relate to setting thresholds and holdover quantities that affect how orders are placed. As such, Applicant respectfully submits that the rejection of claims 29, 49, and 77 is in error because the Final Office Action provides no rationale as to why a person having ordinary skill in the art would modify the order threshold percentage and holdover tracking features of Colella to perform a stand by requirement calculation.

XIII. The Colella and Gardner references fail to render independent claim 16 obvious because those references fail to render obvious the concept of using two reports to assess whether a given pharmaceutical order is entitled to an "own use" discount.

Claim 16 is directed to a method that improves the reliability of an "own use" status determination for an order from a buyer by requiring that both a "first associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with

pharmaceuticals" by the buyer and a "second associated report summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals" by the buyer be analyzed to determine whether the order qualifies for an "own use" discount.

With respect to the scope and content of the prior art, Colella discloses that a patient's drug needs are tracked as a result of data entry by health care providers through the DDMs. (See Colella; col. 4, lines 1-9). Colella further teaches that the DIMS program running on the CPC will aggregate the patient needs reported through the DDMs to generate a purchase order for drugs to be placed with the DCC. (See Colella, col. 4, lines 10-26; col. 5, lines 33-43). Gardner states that purchase orders should be inspected for "lack of documentation" to assess whether diversion may be occurring, but does not elaborate on what documentation should be inspected. (See Gardner; p. 74).

Applicant respectfully submits that, at best, a person having ordinary skill in the art would be motivated by Gardner to inspect Colella's purchase orders against the DDM records to assess whether any diversion of the hospital's inventory may be occurring. There is no teaching, suggestion, or motivation in either Colella or Gardner for using a second report that summarizes the patient's drug needs to add reliability to the audit process through redundancy. Moreover, the Final Office Action fails to provide any reason for a person having ordinary skill in the art to analyze orders against not only a report based on the DDM records but also against a second report independently of the teachings, suggestions, and motivations found in the Colella and Gardner references. Instead, the Final Office Action contends that Colella discloses the use of the second report at col. 8, lines 41-67, wherein this second report is analyzed to assess whether it supports the order. However, Applicant interprets this passage as describing the interface screen for reviewing "items that have been ordered through the DDM system". (See Colella; col. 8, lines 41-42; Figure 6). Thus, the information contained in the interface screen of Figure 6 relates to an already placed order and is not used to make a status determination as to whether the buyer qualifies for an "own use" discount. Once again, Colella's orders are presumed to be entitled to the "own use" discount so no analysis would be necessary to make the status determination of claim 16. Furthermore, Applicant notes that the information in the interface screen of Figure 6 does not include sufficient information from which to judge whether an order is entitled to an "own use" discount. It can be seen that the

interface screen of Figure 6 ***does not in fact indicate the quantity of each item that has been ordered*** and thus would not be useful for the analyzing step recited in claim 16. While the screen indicates the previous purchase order (PO) in which each listed drug was ordered, the screen ***fails to identify the actual quantity ordered for each item***. The "TR QUAN" field is described at col. 8, lines 59-67 as identifying only the holdover quantity for the item, which represents the current inventory overstock. For example, item 1015130 is listed with a TR QUAN value of "100 20", which Applicant interprets as a holdover overstock of 20 tablets relative to a 100 count bottle. (See Colella; col. 7, lines 12-20). The "ORD" field is described as identifying the ordering threshold percentage for the associated item. (See Colella; col. 9, lines 1-4). Applicant further notes that the "ITEM" field and the "STK#" field are used to list the identifiers for the drug referenced in the "DESCRIPTION" field, as used by the DDMs and DCC respectively. (See Colella; col. 8, lines 50-54; col. 6, lines 6-7). Thus, Applicant interprets the ITEM and STK# fields as also failing to convey the actual quantity of each drug in a given purchase order. This failure is understandable as Colella discloses that the role of the interface screen of Figure 6 is not for comparison against orders, but rather its "purpose ... is to allow review, and if necessary, adjustments to the carryover quantity and ordering threshold for a particular item." (See Colella; col. 8, lines 41-44). Therefore, Applicant respectfully submits that the Final Office Action is in error when it asserted that Colella discloses the analysis of two reports to assess whether the reports support the order; as such, Applicant respectfully submits that claim 16 is patentable over the Colella/Gardner combination because the Final Office Action provides no rationale as to why a person having ordinary skill in the art would find it obvious to analyze two reports summarizing a patient's "own use" needs when assessing whether a pharmaceutical order is entitled to an "own use" discount.

XIV. The Colella and Gardner references fail to render dependent claim 17 obvious.

Dependent claim 17 further recites the step of "placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount." This claim is further distinguishable over the Colella/Gardner combination. As indicated above, the

interface screen of Figure 6 which the Examiner has equated to the "second associated report" of claim 16 is described by Colella as pertaining to items that have already been ordered. However, with claim 17, the order is not placed until after the two reports have been analyzed and a status determination as to the "own use" discount eligibility is made. This represents an entirely different mode of operation than the Colella/Gardner combination, which presupposes that orders are entitled to "own use" discounts, and wherein audits are conducted on the hospital's inventory to assess whether an diversion has been occurring after orders have been filled. Therefore, Applicant respectfully submits that claim 17 is also patentable over the Colella/Gardner combination.

XV. The Colella and Gardner references fail to render independent claim 69 obvious.

Independent claim 69 includes limitations similar to claim 16, namely, claim 69 requires that the "own use" audit be based on at least two types of audit data. As such, because Gardner is silent as to the "documentation" to be used for inspecting purchase orders and because Colella discloses only one form of potential audit data (the DDM records), Applicant respectfully submits that claim 69 is also patentable over the Gardner/Colella combination for the reasons set forth above with respect to claim 16.

XVI. The Colella and Gardner references fail to render dependent claims 70 and 79 obvious.

Dependent claims 70 and 79 require that the "own use" audit utilize a "retail pharmacy listing". As previously explained in connection with claim 1, the cited references are silent with respect to how retail pharmacies can obtain "own use" discounts. In this silence, the cited references further fail to render obvious the concept of using the retail pharmacy listings recited in claims 70 and 79 to establish that an order is entitled to an "own use" discount. Therefore, Applicant further submits that the obviousness rejection of claims 70 and 79 are in error and must be reversed.

XVII. The Colella and Gardner references fail to render dependent claim 64 obvious.

Claim 64 requires that the information used to assess the order's entitlement to an "own use" discount comprises "information from at least one POS" **and** "information from at

least one MAR". POSs and MARs are described in the patent application with reference to Figures 3-4. The citations by the Examiner to Colella for rejecting claim 64 point not to POSs and MARs but rather to the interface screens of Figures 5-6. Therefore, Applicant respectfully submits that the obviousness rejection of claim 64 is deficient because the Examiner has announced no rationale for a person having ordinary skill in the art to use POSs and MARs for an audit. Furthermore, the Examiner has misinterpreted claim 64 to require information from a POS or information from an MAR. This error by the Examiner also establishes the error of claim 64's obviousness rejection.

XVIII. The Colella, Gardner, and Spurgeon references fail to render claims 2-8, 11, 14, and 38-44 obvious.

For the same reasons expressed above in connection with the claims from which claims 2-8, 11, 14, and 38-44 depend, Applicant respectfully submits that the obviousness rejections of claims 2-8, 11, 14, and 38-44 are in error and must be reversed. The Spurgeon reference relates to a system for processing health care insurance information. Spurgeon was cited by the Examiner only in connection with claim limitations relating to computer networking and file format conversions. (See Final Office Action; p. 27-36). As such, Spurgeon is not germane to the issues discussed above in connection with Colella and Gardner regarding "own use" audits.

viii. Claims Appendix:

1. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical, wherein said buyer comprises one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical;

receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

comparing said order with said associated report to determine whether said associated report supports said order; and

responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount.

2. The method of claim 1 wherein the step of receiving said order further comprises receiving said order on a computer as a transmission over the internet.

3. The method of claim 2 wherein the step of receiving said associated report further comprises receiving said report as at least one computer file, and wherein the comparison step is performed by a software program executed on said computer.

4. The method of claim 3 further comprising the step of converting said at least one computer file to a format readable by said software program.

5. The method of claim 2 further comprising the step of entering said associated report as data into said computer, and wherein the comparison step is performed by a software program executed on said computer.

6. The method of claim 2 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and

comparing said second associated report with said order or with said associated report using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

7. The method of claim 6 wherein the comparing step between said second associated report and said order is performed by a software program executed on said computer, the method further comprising the step of converting said at least one computer file to a format readable by said software program.

8. The method of claim 2 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

entering said second associated report as data into said computer; and

comparing said second associated report with said order or with said associated report using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

9. The method of claim 1 further comprising the step of entering said order as data into a computer.

10. The method of claim 9 wherein the step of receiving said associated report further comprises receiving said report as at least one computer file, and wherein the comparison step is performed by a software program executed on said computer.

11. The method of claim 10 further comprising the step of converting said at least one computer file to a format readable by said software program.

12. The method of claim 9 further comprising the step of entering said associated report as data into said computer, and wherein the comparison step is performed by a software program executed on said computer.

13. The method of claim 9 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and

comparing said second associated report with said order or with said associated report using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

14. The method of claim 13 wherein the comparing step between said second associated report and said order is performed by a software program executed on said computer, the method further comprising the step of converting said at least one computer file to a format readable by said software program.

15. The method of claim 9 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

entering said second associated report as data into said computer; and

comparing said second associated report with said order using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

16. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;

receiving a first associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

receiving a second associated report summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals by said buyer;

analyzing said first associated report and said second associated report to determine an extent to which they support said order; and

responsive to said determined extent, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount.

17. The method of claim 16 further comprising the step of placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount.

18. The method of claim 17 further comprising the step of sending either said first associated report or said second associated report, or both said first and second associated reports, to said pharmaceutical seller.

19. The method of claim 17 further comprising the step of allowing said pharmaceutical seller to have access to either said first associated report or said second associated report or both said first and second associated reports.

20. The method of claim 1 further comprising the step of placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount.

21. The method of claim 20 further comprising the step of sending said associated report to said pharmaceutical seller.

22. The method of claim 20 further comprising the step of allowing said pharmaceutical seller to have access to said associated report.

23. The method of claim 20 further comprising the steps of generating a status report and sending said status report to said pharmaceutical seller.

24. CANCELED

25. The method of claim 20 further comprising the step of arranging for said pharmaceutical seller to directly ship an appropriate quantity of said type of pharmaceutical directly to one of a group consisting of:

an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical;

at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical; and

at least one nursing home having at least one patient needing said type of pharmaceutical.

26. CANCELED

27. The method of claim 1 further comprising the step of generating a status report.

28. The method of claim 1 further comprising, in response to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

29. The method of claim 28 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer.

30. A pharmaceutical order auditing system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said pharmaceutical order auditing system comprising:

a first input for receiving pharmaceutical order data, said order data comprising a type of pharmaceutical, a quantity of said type of pharmaceutical, and a buyer requesting said quantity of said type of pharmaceutical;

a second input for receiving audit data, said audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount;

a processor;

software that is executed on said processor, the software being configured to (1) confirm whether said buyer is any of a group consisting of (a) an entity comprised of at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (b) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical, and (2) compare said order data with said audit data to make a status determination whether said buyer qualifies for purchasing said quantity at said reduced price, said status determination depending upon said confirmation and said comparison between said order data and said audit data; and

an output for communicating said status determination to a user.

31. CANCELED

32. The pharmaceutical order auditing system of claim 30 wherein said audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

33. The pharmaceutical order auditing system of claim 30 further comprising a third input for receiving additional audit data, said additional audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount, and wherein said software is further configured to compare said additional audit data with said order data or with said audit data in making said status determination, said status determination further depending upon said additional audit data comparison.

34. The pharmaceutical order auditing system of claim 33 wherein said additional audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

35. The pharmaceutical order auditing system of claim 30 wherein said audit data comprises a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said order data with said audit data, said status determination depending upon whether said comparison between said order data and said audit data results in a sufficient correlation between said order data and said audit data for said buyer to qualify for said discount.

36. The pharmaceutical order auditing system of claim 35 further comprising a third input for receiving additional audit data, said additional audit data comprising a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said additional audit data with said

order data or with said audit data, said status determination further depending upon said additional audit data comparison.

37. The pharmaceutical order auditing system of claim 35 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers.

38. The pharmaceutical order auditing system of claim 35 further comprising a converter configured to convert said audit data to a common format.

39. The pharmaceutical order auditing system of claim 38 wherein said audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

40. The pharmaceutical order auditing system of claim 38 further comprising a third input for receiving additional audit data, said additional audit data comprising a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said additional audit data with said order data or with said audit data, said status determination further depending upon said additional audit data comparison.

41. The pharmaceutical order auditing system of claim 40 wherein said additional audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

42. The pharmaceutical order auditing system of claim 40 wherein said converter is further configured to convert said additional audit data to a common format.

43. The pharmaceutical order auditing system of claim 40 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said additional audit data further comprises each of a plurality of identifiers for said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said additional audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said additional audit data patient identifiers and said order data patient identifiers.

44. The pharmaceutical order auditing system of claim 38 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers.

45. The pharmaceutical order auditing system of claim 30 wherein said output is communicated to said user as a status report.

46. The pharmaceutical order auditing system of claim 30 further comprising a third input for receiving additional audit data, said additional audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount, and wherein said software is further configured to compare said additional audit data with said order data or with said audit data in making said status determination, said status determination further depending upon said additional audit data comparison.

47. The pharmaceutical order auditing system of claim 30 wherein said software is further configured to allow for a tolerance in making said status determination.

48. The pharmaceutical order auditing system of claim 30 wherein said software is configured to adjust said order so that there is a sufficient match between said adjusted order and said audit data if said buyer does not qualify for said buyer does not qualify for said discount on the basis of said unadjusted order.

49. The pharmaceutical order auditing system of claim 48 wherein said software is configured to calculate a stand by requirement for said buyer if said order needs adjustment.

50-61. CANCELED

62. A computer-implemented method for processing pharmaceutical orders to determine whether said orders qualify for an "own use" discount, said method comprising:

determining an "own use" discount status for a proposed "own use" purchase by a buyer of a quantity of a type of pharmaceutical on the basis of a comparison between the proposed purchase and information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with the pharmaceutical by the buyer; and

wherein said buyer comprises at least one selected from the group consisting of (1) a retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) an entity comprising a plurality of said retail pharmacies.

63. The method of claim 62 wherein said information comprises at least one selected from the group consisting of information from a retail pharmacy that summarizes a pharmaceutical need by at least one hospital, nursing home, or long term health care facility where said at least one patient resides, information from at least one physician order sheet (POS), and information from at least one medication administration record (MAR).

64. The method of claim 63 wherein said information comprises information from at least one POS and information from at least one MAR.

65. The method of claim 63 wherein said buyer comprises said retail pharmacy.

66. The method of claim 63 wherein said buyer comprises said entity.

67. CANCELED

68. The method of claim 63 further comprising:

if said quantity for said proposed purchase does not qualify for an "own use" discount, (1) determining, on the basis of said comparison, a subquantity of said quantity that does qualify for said "own use" discount and (2) adjusting said quantity for said proposed purchase to match said subquantity.

69. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:

a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount, said audit being based on at least two types of audit data that are compared to said order.

70. The system of claim 74 further comprising:

a second computer in communication with said computer via a network, said second computer being configured to provide said computer with said retail pharmacy listing, and

wherein the computer is further configured to perform said "own use" audit by comparing said order with said said retail pharmacy listing.

71. The system of claim 70 wherein said nursing home data comprises at least one selected from the group consisting of information from a physician order sheet (POS) corresponding to said at least one patient and information from a medication administration record (MAR) corresponding to said at least one patient.

72. The system of claim 71 wherein said buyer is one of a group consisting of:

an entity comprising a plurality of retail pharmacies that supply pharmaceuticals to at least one hospital, nursing home, or long term health care facility;

at least one retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility;

at least one hospital;

at least one nursing home; and

at least one long term health care facility.

73. The system of claim 69 wherein said order comprises an order for a quantity of pharmaceuticals, and wherein the computer is further configured to perform said "own use" audit by:

in response to said audit resulting in a determination that said quantity for said order does not qualify for an "own use" discount, determining whether a subquantity of said quantity does qualify for said "own use" discount; and

in response to said subquantity determining step resulting in a determination that a subquantity of said quantity does qualify for said "own use" discount, adjusting said quantity for said order to match said subquantity.

74. The system of claim 69 wherein said at least two types of audit data comprise:

a retail pharmacy listing that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals; and

data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.

75. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:

a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount;

wherein said order comprises an order for a quantity of pharmaceuticals; and

wherein the computer is further configured to perform said "own use" audit by: (1) in response to said audit resulting in a determination that said quantity for said order does not qualify for an "own use" discount, determining whether a subquantity of said quantity does qualify for said "own use" discount, and (2) in response to said subquantity determining step

resulting in a determination that a subquantity of said quantity does qualify for said "own use" discount, adjusting said quantity for said order to match said subquantity.

76. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;

receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

comparing said order with said associated report to determine whether said associated report supports said order;

responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount; and

responsive to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

77. The method of claim 76 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer.

78. The method of claim 62 wherein said information comprises at least two selected from the group consisting of information from a retail pharmacy that summarizes a pharmaceutical need by at least one hospital, nursing home, or long term health care facility where said at least one patient resides, information from at least one physician order sheet (POS), and information from at least one medication administration record (MAR).

79. The method of claim 16 wherein said first associated report comprises listing from a retail pharmacy that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals, and wherein said second associated report comprises data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.

80. The method of claim 79 wherein the second associated report data comprises data from a physician order sheet (POS) or data from a medication administration record (MAR).

ix. Evidence Appendix:

Enclosed herewith as Exhibits A-C, respectively, are copies of the Colella, Gardner, and Spurgeon references cited by the Examiner in the first Office Action and the Final Office Action.

x. Related Proceedings Appendix:

None.

For the foregoing reasons, Applicant respectfully submits that the Examiner's rejections as to all pending claims in this patent application are in error and must be reversed. Favorable action is respectfully requested.

Respectfully submitted,

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